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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,957	06/18/2001	Rose Ramon Botella Mesa	229752001300	3466

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,957

Applicant(s)

BOTELLA MESA ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2005 and 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7,9,11-15 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,11-15 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

This office action is in response to an amendment filed 2/9/06 and request for continued examination filed 3/9/06. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/06 has been entered. Claims 2-6, 8, 10, 16-18 and 25 have been cancelled. Claims 1, 7, 11 and 15 have been amended. Claims 1, 7, 9, 11-15 and 19-24 are pending in the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action mailed 9/9/06 and restated below.**

The limitation that the nucleotide sequence is "residues +1 to -368" or a homolog of, complement of or sequences capable of hybridizing to "at least residues +1 to -368" has been

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added to claim 1, 7 and 15. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for the term “residues +1 to -368” specifically because SEQ ID NO:3 comprises amino acids 1 to 2474. Therefore, the limitation of “residues +1 to -368” is impermissible NEW MATTER.

### ***Response to Argument***

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph on page 6 of the amendment filed 2/9/06. Applicants argue that they have removed of the phrase “at least” to put the claims in condition for allowance.

Applicants’ arguments filed 2/9/06 have been fully considered but they are not persuasive. The claim recites a fragment of SEQ ID NO:3, the fragment is said to comprise residues +1 to -368. However SEQ ID NO:3 is comprised of residues 1 to 2474 and cannot possible comprise -368. -368 is a designation limited to the gene and not a construct such as SEQ ID NO:3. It would be remedial to indicate which residues in SEQ ID NO:3 are the part of the recited promoter and not what region of the gene.

### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid sequence defining a

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promoter comprising SEQ ID NO:3, does not reasonably provide enablement for said sequence with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new rejection.**

**1) Nature of invention.** The invention is drawn to an isolated sequence that defines a promoter in which the promoter is said to direct expression of a gene encoding ACC synthase and is inducible in response to physical stimulation.

**2) Scope of the invention.** In claim 1, 7 and 15, applicants claim a genus of sequences that are nucleotide sequences that “define a promoter”, said sequence with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C. Therefore, applicants recite a broad and diverse genus of sequences that are nucleotide sequences that “define a promoter”, said sequence with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C.

**3) Number of working examples and guidance.** Functionally, applicants disclose that sequences that “define a promoter” “confers, activates or enhances expression of a structural gene or other nucleic acid in a plant cell” (see page 16, paragraph 5). Structurally, applicants disclose the sequence of pGEL-1 (SEQ ID NO:3). pGEL-1 comprises the promoter from mung bean ACC synthase that directs expression of a protein encoded by a sequence with 100%

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identity to SEQ ID NO: 1. Primer pairs 4 and 5 that are used to isolate the promoter from mung bean. To characterize the promoter, applicants generate a series of seven serial deletions of the mung bean ACC synthase promoter region (page 36). A general decline in activity in the shorter promoters is detected in immature and mature leaf tissue but not evidently in any other tissues (page 37).

**4) State of the art.** The art does not disclose SEQ ID NO:3. Nor does the art or the specification teach the acc synthase promoter from mung bean or domains/ motifs required for promoter activity by the acc synthase promoter. Therefore, as neither domains nor structural motifs are available, the ability to identify structurally those molecules that functionally meet the claim limitations is highly unpredictable. Isolation of sequences with even minor changes in sequence has profound effects on the resulting protein. Isolation by structural similarity results in a collection of sequences for which functional data is unavailable. The ability to identify *a priori* those molecules from a broad and diverse collection of molecules that function as a promoter is highly unpredictable. A review of the art demonstrates that the ability to *de novo* protein model is not routine but requires vast computation skills (see Protein structure prediction, page 2, first paragraph). This article also teaches that prediction methods that rely on comparative protein modeling allow similar domains or structures to allow identification of three-dimensional models (see Protein structure prediction, page 2, first paragraph). However, as demonstrated by Smith et al, even a single mutation can greatly effect even simple structural formations of the resultant protein. This is explained in the review titled Tertiary structure that teaches mutations in genes encoding proteins can result in degradation or lack of transport or aggregation into insoluble deposits of the resulting protein (begin page 1, last paragraph).

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**5) Unpredictability of the art.** By reciting sequences with 90% homology to SEQ ID NO:3 or the fragment comprising +1 to -368, applicants recite a broad genus of promoters that can differ in any of 10% of the nucleotides of SEQ ID NO:3. Furthermore, by claiming sequences hybridizing under medium stringency conditions (according to page 13, 6X SSC, 0.1% w/v SDS and 45°C), the relationship between the structure of the sequence and its function becomes unclear. Furthermore, applicants do not provide the structural requirements of the sequences of SEQ ID NO:3 that “confers, activates or enhances expression of a structural gene or other nucleic acid in a plant cell”. Therefore, it would require undue experimentation to identify those molecules that are 90% identical to SEQ ID NO:3 or that are isolated upon hybridization to SEQ ID NO:3 or homologs of SEQ ID NO:3. A person of ordinary skill in the art could not predict the operability of the species that would be isolated of sequences with at least 90% similarity or a complement of this sequence of a sequence of nucleotides that hybridize to SEQ ID NO:3 under stringency conditions of 2X SSC, 0.1% w/v SDS at 45°C. By disclosing pGEL-1, the applicants have not reduced to practice the claimed invention.

**6) Amount of Experimentation Required.** The specification provides a single reference sequences without identifying relevant characteristics or structural-functional relationships. Thus neither the specification nor the prior art teach the structural requirements of sequences with at least 90% similarity to SEQ ID NO:3 or to +1 to -368 or a complement of these sequences or a sequence of nucleotides that hybridize to these sequences under stringency conditions of 2X SSC, 0.1% w/v SDS and 45°C that encodes a promoter. Given the large size and diversity of the recited sequences, the absence of disclosed or art recognized correlations between structure and function and the large number of potential sequences or homologs, it must

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be considered that any sequence with promoter activity in a plant cell must be empirically determined.

***Response to Amendment-35 USC 112, first paragraph***

Applicants traverse the claim rejections under 35 U.S.C. 35 USC 112, first paragraph on page 6-7 of the amendment filed 2/9/06. Applicants argue that the claims as amended provide the requisite structural characteristic and functional characteristics. Therefore, applicants request the rejection be withdrawn.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive. The rejection of the instant claims is based upon the fact that undue experimentation that would be required to identify the genus of recited sequences given the broad genus of sequences recited coupled with the highly unpredictable nature of the art as set forth above.

***Conclusion***

Claims 1, 7, 9, 11-15 and 19-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
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May 25, 2006

  
**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**